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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/247,406	02/10/99	CAPLAN M	HS105

HM22/0228

PATREA L PABST
ARNALL GOLDEN & GREGORY
2800 ONE ATLANTIC CENTER
1201 WEST PEACHTREE STREET
ATLANTA GA 30309-3450

EXAMINER	
WESSENDORF, T	
ART UNIT	**PAPER NUMBER**
1627	3

DATE MAILED: 02/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applica[illegible]
09/247,406	Caplan
Examiner	**Group Art Unit**
T. Wessendorf	1627

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____1___ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-88* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-88* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

✓ Fax Transmission

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-28, drawn to a method of identifying a mutant polypeptide, classified in class 435, subclass 7.1.

II. Claims 29-32, drawn to a polypeptide, classified in class 530, subclass 388.1+.

III. Claims 33-38, drawn to a fusion protein and composition, classified in class 424, subclass 134.1.

IV. Claims 39-41, drawn to a nucleic acid, classified in class 536, subclass 23.4.

V. Claims 42-43, drawn to a transgenic plant, classified in class 800, subclass 895.

VI. Claims 44-45, drawn to transgenic animal, classified in class 800, subclass 13.

VII. Claims 46-53, drawn to a method of identifying mutant to an allergen, classified in class 435, subclass 7.1.

VIII. Claims 54-60, drawn to a method of treating, classified in class 514, subclass 2+.

IX. Claims 61-78, drawn to a method of identifying fusion proteins, classified in class 435, subclass 7.1.

X. Claims 79-88, drawn to a method of identifying fusion protein that has reactivity other than an antibody, classified in class 435, subclass 4+ .

The inventions are distinct, each from the other because of the following reasons:

Inventions I, VII, VIII, IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different

inventions are independent methods having different modes of operation and practicing the method yield different products.

Inventions II, III, IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are independent compounds having different structure and/or functions, modes of operation and may possibly yield different effects.

Inventions (I, VII, VIII, IX and X) and (II, III, IV, V and VI) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the different processes as claimed can be used to make other and materially different products having different structures.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims 14 and 87 are generic to a plurality of disclosed patentably distinct species comprising compounds having the different activities:

1. Enzyme
2. Receptor
3. Anticancer
4. Immunosuppressive
5. Immunostimulatory
6. Antibiotic
7. Antiviral
8. Trophic activity

Each of these species possesses different activities that utilizes different compounds that might have different structures and therefore different functions and modes of action or operation. A prior art reference to e.g., anticancer compound would not render obvious or anticipate a compound with an antiviral compound. Therefore, the species would require

different patentability determinations under the different statutes.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1627.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number for this Group is (703) 308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Tdw

2/25/00

T. Wessendorf

Patent Examiner

Attorney Docket No.: 5676.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Olsen et al.

Confirmation No: 7645

Serial No.: 09/417,608

Group Art Unit: 1627

Filed: October 13, 1999

Examiner: Bennett Celsa

For: Low Allergenic Protein Variants

AMENDMENT UNDER 37 C.F.R. 1.111

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Office Action mailed August 29, 2001, please amend the above-identified application as follows:

IN THE CLAIMS:

Please cancel claims 35-54 without prejudice or disclaimer. Please add new claims 55-73:

55. A method of producing a protein variant, comprising the steps of:

(a) subjecting a random peptide display package library to one or more antibodies to identify regions of peptides that bind to the one or more of the antibodies;

(b) identifying one or more epitope patterns by aligning the peptides that bind to the one or more of the antibodies;

(c) obtaining a three-dimensional structure of a parent protein;

(d) identifying the one or more epitope patterns on the three-dimensional structure of the parent protein;

(e) identifying an epitope area of amino acids situated within 5 Å of any amino acid of the one or more epitope patterns of the parent protein; and

(f) modifying one or more amino acids identified in step (e) of the parent protein to form the protein variant, wherein the protein variant retains functionality of the parent protein and has a lower immunogenicity than the parent protein.

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56. The method of claim 55, wherein the protein variant has a lower allergenicity than the parent protein.

57. The method of claim 55, wherein the one or more antibodies are raised against the parent protein.

58. The method of claim 55, wherein the parent protein is an enzyme.

59. The method of claim 58, wherein the enzyme is a carbohydrase, glycose isomerase, glycosyl hydrolase, lipase, oxidoreductase, peroxidase, phytase, polysaccharide lyase, protease, or transglutaminase.

60. The method of claim 55, wherein the one or more antibodies are IgG or IgE antibodies.

61. The method of claim 55, wherein the peptide display package library is a phage display library.

62. The method of claim 55, wherein the peptides of the peptide display package library are oligopeptides having from 5 to 25 amino acids.

63. The method of claim 55, wherein the epitope area is changed by substituting at least one amino acid of the epitope area.

64. The method of claim 55, wherein the epitope area is changed by adding or deleting at least one amino acid of the epitope area.

65. The method of claim 55, wherein the epitope pattern is changed by substituting at least one amino acid of the epitope pattern.

66. The method of claim 55, wherein the epitope pattern is changed by adding or deleting at least one amino acid of the epitope pattern.